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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Applicant : Shinichi TAKAMOTO et al.

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TRANSMITTAL OF ENGLISH LANGUAGE TRANSLATION OF PRIORITY APPLICATION & STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

June 22, 2005

Sir:

Applicants submit herewith English language translations of the Japanese priority applications, Japanese Patent Application Nos. 2002-315449 and 2003-300723 for the United States patent application identified above, with statements that the translations are accurate. A claim to priority was filed on October 29, 2003.

In the event any fees are required, please charge our Deposit Account No. 111833.

Respectfully submitted,

KUBOVCIK & KUBOVCIK

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U.S Patent S.N. 10/695,460
ENGLISH LANGUAGE TRANSLATION
OF PRIORITY APPLICATION & STATEMENT
Atty. Dkt. NPR-127

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Enclosure: English Language Translations of Priority Applications (JP 2002-315449 and JP 2003-300723) w/ Statements

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STATEMENT

I, Ryohei NAMBA, hereby state that I am competent in both the Japanese and English languages and that the attached English language document is an accurate translation of Japanese Patent Application No. 2003-300723.

Date: September 29, 2003

Name: Ryohei Namba

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【Name of the Document】 PATENT APPLICATION

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【Destination】 Commissioner of the Japan Patent Office

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【Claiming of Priority Based on Earlier Application】

【Application No.】 JP2002-315449

【Date of Application】 October 30, 2002

【Notification of Fee】

【Deposit List No.】 003919

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【List of Documents Attached】

【Name of Document】 Scope of Claims 1

【Name of Document】 Specification 1

【Name of Document】 Drawings 1

【Name of Document】 Abstract 1

【Name of the Document】 Scope of Claims

【Claim 1】

A graft grasping device, comprising graft grasping means that grasps a graft in a lumen softly and includes a soft tubular member capable of expanding a diameter of the lumen easily, and suction force transmission means which communicates with the lumen of the graft grasping means, wherein while a graft is held in the lumen, a suction force transmitted from the suction force transmission means widely acts on an inside of the lumen.

【Claim 2】

A graft grasping device according to Claim 1, comprising:

a graft grasping member including a soft tubular grasping portion having a substantially C-shaped cross section and a slit in a longitudinal direction; and

a suction tube communicating with the lumen of the grasping portion and connected to a side wall of the grasping portion, wherein:

an inner wall of the grasping portion has at least a recessed portion including a communication portion with a lumen of the suction tube;

the recessed portion is covered with a sheet having a plurality of pores; and

a mesh sheet is existent in a space defined between the recessed portion and the sheet.

【Claim 3】

A graft grasping device according to Claim 2, wherein the recessed portion is formed on the entire inner wall excluding portions adjacent to a distal end and a proximal end of the grasping portion and portions adjacent to the slit.

【Claim 4】

A graft grasping device according to Claim 2 or 3, wherein at least one end face of the grasping portion is formed obliquely with respect to the longitudinal direction of the grasping portion.

【Claim 5】

A graft grasping device according to any one of Claims 2 to 4, wherein the side wall of the grasping portion is provided with a grip.

【Claim 6】

A graft grasping device according to Claim 5, wherein the grip is connected to a suction tube connection portion provided on the side wall of the grasping portion concentrically to the suction tube.

【Claim 7】

A graft grasping device according to any one of Claims 2 to 6, wherein a connector is provided at a proximal end of the suction tube.

【Name of the Document】 Specification

【Title of the Invention】 Graft grasping device

【Technical Field】

【0001】

The present invention relates to a graft grasping device. More specifically, the present invention relates to a graft grasping device capable of grasping a graft having an open anastomosing port by negative pressure when coronary artery bypass grafting is carried out.

【Background Art】

【0002】

In order to treat ischemic heart diseases such as angina pectoris and myocardial infarct, percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafting (CABG) are carried out, out of which little invasive PTCA has been very popular in recent years. However, CABG is suitably selected for patients having a lesion in the left main coronary artery, patients having a lesion in the 3 major ramuses, and patients who suffer from restenosis very often after PTCA. Currently, CABG is carried out on about 15,000 patients a year in Japan and about 10 times more patients in Europe and the US.

【0003】

CABG is carried out by a surgeon, in which part of an autograft such as a great saphenous vein is used as a bypass graft under general

anesthesia. More specifically, one end of the bypass graft is sutured with the aorta and the other end is sutured with a region after the stenosis portion of the coronary artery. After CABG, the blood bypasses the stenosis portion and runs from the aorta to the myocadium through the newly transplanted bypass graft.

【0004】

When the bypass graft is anastomosed with the aorta or the coronary artery, it must be grasped while its anastomosing port is open. Therefore, a pair of tweezers or the like have been conventionally used. However, grasping with the tweezers or the like may damage the intima of the bypass graft. This is because the ends of the tweezers are contacted to the intima of the graft. Also, most of the tweezers or the like are made from a hard material such as a metal and made uneven to prevent slipping in most cases. Thus, there is a fear that the intima of the graft may be further damaged. When the intima of the bypass graft is damaged, the adhesion of a thrombus to the damaged part or intimal thickening may occur, thereby increasing the possibility of causing restenosis. When restenosis occurs, a surgical operation is needed again, thereby increasing a burden on a patient. Also, in the case where only part of the anastomosing port is grasped with the tweezers, the anastomosing port of the bypass graft cannot be opened wide.

【0005】

In view of the above, there has been made an invention in which

a bypass graft is suction-grasped by a grasping portion composed of a circular hollow tube having a plurality of suction ports in the inner wall as a graft grasping device used in place of the conventional tweezers (see Patent Document 1).

【0006】

【Patent Document 1】 JP 2002-360593 A

【Disclosure of the Invention】

【Problem to be solved by the Invention】

【0007】

However, since the graft grasping device of Patent Document 1 has a tubular grasping portion, when the bypass graft is suction-grasped, a contact area between the grasping portion and the graft is small, causing a fear that the graft may be separated from the grasping portion by a small force during a surgical operation. That is, when sufficiently high operation ease is to be obtained while the graft is grasped, the contact area between the grasping portion and the graft must be large. Also, to insert a graft having almost the same diameter as the inner diameter of the grasping portion, the grasping portion must be opened wide. To open the grasping portion wide, the grasping portion must be made from a material having sufficiently high flexibility. However, when such a soft flexible material is used in the grasping portion, the grasping portion may be crushed by a suction force, causing a fear that the bypass graft may not be suction-grasped. The graft grasping device

of Patent Document 1 is not provided with means for preventing the crushing of the grasping portion. Further, the anastomosing port of the bypass graft is cut obliquely in most cases to ensure a flow of the running blood. To suction-grasp this bypass graft, it must be grasped at a position away from the end of the anastomosing port. In this case, there is another fear that the anastomosing port may not be opened wide.

【Means for solving the Problem】

【0008】

Accordingly, the inventors of the present invention have made extensive studies with a view to solving the above-mentioned problems. As a result, the present invention is completed. That is, the present invention relates to:

(1) a graft grasping device, including graft grasping means that grasps a graft in a lumen softly and includes a soft tubular member capable of expanding a diameter of the lumen easily, and suction force transmission means which communicates with the lumen of the graft grasping means, in which while a graft is held in the lumen, a suction force transmitted from the suction force transmission means widely acts on an inside of the lumen;

(2) A graft grasping device according to (1) above, including:

a graft grasping member including a soft tubular grasping portion having a substantially C-shaped cross section and a slit

in a longitudinal direction; and

a suction tube communicating with the lumen of the grasping portion and connected to a side wall of the grasping portion, in which:

an inner wall of the grasping portion has at least a recessed portion including a communication portion with a lumen of the suction tube;

the recessed portion is covered with a sheet having a plurality of pores; and

a mesh sheet is existent in a space defined between the recessed portion and the sheet.

(3) A graft grasping device according to (2) above, in which the recessed portion is formed on the entire inner wall excluding portions adjacent to a distal end and a proximal end of the grasping portion and portions adjacent to the slit.

(4) A graft grasping device according to (2) or (3) above, in which at least one end face of the grasping portion is formed obliquely with respect to the longitudinal direction of the grasping portion.

(5) A graft grasping device according to any one of (2) to (4) above, in which the side wall of the grasping portion is provided with a grip.

(6) A graft grasping device according to (5) above, in which the grip is connected to a suction tube connection portion provided

on the side wall of the grasping portion concentrically to the suction tube.

(7) A graft grasping device according to any one of (2) to (6) above, in which a connector is provided at a proximal end of the suction tube.

【Effect of the Invention】

【0009】

According to the present invention, a graft can be grasped by a graft grasping device making use of a suction force generated by negative pressure, thereby eliminating the fear that the intima of the graft is damaged, which is a problem to be solved in the method of the prior art using tweezers or the like. Further, the graft can be grasped while the anastomosing port of the graft is opened, thereby making it possible to anastomose grafts with each other reliably and easily. Particularly, the graft grasping device of the present invention can be advantageously used in CABG.

【Best Mode for carrying out the Invention】

【0010】

Embodiments of the present invention will be described hereinbelow with reference to the accompanying drawings.

Fig. 1 is a front view of an embodiment of the present invention, Fig. 2 is a left side view of Fig. 1, Fig. 3 is an A-A cross sectional view of Fig. 1, Fig. 4 is an enlarged view of a main portion of Fig. 3, and Fig. 5 is an enlarged B-B cross sectional view of Fig.

2. In addition, Figs. 6 to 9 are diagrams for explaining CABG using the graft grasping device of the present invention. Fig. 10 is a diagram showing how to cut a graft obliquely. The section of the graft forms a smooth hood-like anastomosing port having a large opening area. Fig. 11 is a front view of another embodiment of the present invention, and Fig. 12 is a diagram for explaining a use state of Fig. 11.

【0011】

As shown in Figs. 1 to 5, the graft grasping device of the present invention includes a graft grasping member 1 including a soft tubular grasping portion 11 having a substantially C-shaped cross section and a suction tube 2 which communicates with a lumen 111 of the grasping portion 11 and is connected to a side wall of the grasping portion 11. A recessed portion 114 including at least a communication port 113 which communicates with a lumen 21 of the suction tube 2 and the lumen 111 of the grasping portion 11 is formed on an inner wall of the grasping portion 11. The recessed portion 114 is covered with a porous sheet 13 and a mesh sheet 14 is interposed between the recessed portion 114 and the porous sheet 13.

【0012】

As shown in Figs. 1 and 2, the graft grasping member 1 includes a grasping portion 11 which functions as graft grasping means. The grasping portion 11 is a soft tubular member having a slit 112 in the side wall in a longitudinal direction and has a lumen 111 for

softly grasping a graft. The lumen 111 has a substantially C-shaped cross sectional form due to the formation of the slit 112. The grasping portion 11 can be easily expanded in a diameter by the slit 112 so that the graft can be attached to and detached from the grasping portion 11 by opening the slit 112 before and after the anastomosis of the graft. The slit may be formed at a position where it forms a substantially right angle with the installation angle of a suction tube or a grip to be described hereinafter or may be formed at a position symmetrical thereto. As a result, when the suction tube or grip is pulled, the grasping portion can be thereby easily removed from the graft.

【0013】

A communication port 113 which is a communicating portion with the lumen 21 of the suction tube 2 is formed in the side wall of the grasping portion 11. The communication port 113 is provided with a suction tube connection portion 12 projecting from the side wall of the grasping portion 11. The suction tube connection portion 12 is connected to the suction tube 2. The suction tube connection portion 12 may be connected concentrically to a grip 3 around the suction tube 2 if necessary when a hand of an operator is hard to insert.

【0014】

The grasping portion 11 is generally a tubular member made from a soft flexible resin such as polyurethane, polyethylene or

silicone. As shown in Figs. 3 to 5, a recessed portion 114 includes at least the communication port 113 of the inner wall of the grasping portion 11. The recessed portion 114 is covered with a porous sheet 13 having a plurality of pores 131 and a mesh sheet 14 is inserted into a space between the recessed portion 114 and the porous sheet 13. The length and inner diameter of the grasping portion 11 may be suitably selected according to the diameter of the graft to be used as a bypass. For example, the grasping portion 11 may have a length of about 10 mm and an inner diameter of about 5 mm.

【0015】

It is preferable that the recessed portion 114 is formed large in order that the installation port of the bypass graft grasped by the graft grasping device to the anastomosing part opens large. It is preferably formed in the entire inner wall excluding portions 115 adjacent to the distal and proximal ends of the grasping portion 11 and portions 116 adjacent to the slit 112 so that the suction force of the suction tube 2 acts on substantially the entire graft.

【0016】

The porous sheet 13 is adhered to the inner wall of the grasping portion 11 with portions adjacent to the recessed portion 114 as a margin. In Figs. 4 and 5, the portions 115 adjacent to the distal and proximal ends of the grasping portion 11 and the portions 116 adjacent to the slit 112 serve as the margin. The diameter and the number of the pores 131 of the porous sheet 13 are not particularly

limited if the suction force is widely transmitted to the lumen 111 through the pores 131 and the graft can be grasped softly and reliably. The diameter is suitably about 1 mm and the number of the pores is suitably about 20 to 40. The material for the porous sheet 13 is not particularly limited if it can be adhered or welded to the grasping portion 11 and is preferably the same as the material for the grasping portion 11.

【0017】

The mesh sheet 14 is formed from a material which can adhere to the grasping portion 11 and may be adhered or welded to the grasping portion 11 with stepped portions 117 formed adjacent to the margins 116 and the margins 115 as the margin as shown in Figs. 4 and 5, for example. Alternatively, the mesh sheet 14 may not be adhered to the grasping portion 11 but may be existent in the space between the recessed portion 114 and the porous sheet 13 (in this case, the material therefor is not limited to the material for the grasping portion 11). The stepped portions 117 may be formed adjacent to one or both of the margins 116 and the margins 115.

【0018】

When the graft is suction-grasped, there is a fear that the porous sheet 13 may be brought into close contact with the recessed portion 114 by a negative pressure generated between the lumen 111 and the porous sheet 13. In particular, when the porous sheet 13 is brought into close contact with the recessed portion 114 so as

to fill up the communication port 113, there is a fear that, as the suction force is transmitted only through the pores 131 of the part of the porous sheet 13 corresponding to the communication port 113, a uniform suction force cannot be obtained and the anastomosing port (41 in Fig. 7) of the graft may not be opened. The mesh sheet 14 is means for preventing the porous sheet 13 from being brought into close contact with the recessed portion 114 directly and transmitting the suction force to the pores 131 of the porous sheet 13 other than the part corresponding to the communication port 113 through the mesh. According to the constitution including the recessed portion 114, the porous sheet 13, and the mesh sheet 14, while the graft (4 in Fig. 6) is held within the lumen 111 (not grasped yet), the suction force transmitted from the suction tube 2 widely acts on the inside of the lumen 111. That is, in this constitution, the wall of the lumen 111 of the grasping portion 11 is the inner surface of the porous sheet 13. While the graft (see 4 in Fig. 6) is held in the lumen 111, the suction force transmitted to the recessed portion 114 of the grasping portion 11 from the communication port 113 through the lumen 21 of the suction tube 2 widely acts on the inside of the lumen 111 through the mesh sheet 14 and the pores 131 of the porous sheet 13. Then, the graft is uniformly dilated by the transmitted suction force and adsorbed to the inner surface of the porous sheet 13 and put into a state of being grasped to the grasping portion 11.

【0019】

The suction tube 2 is made from a flexible resin such as polyurethane, polyethylene, polyester, polypropylene, polyamide, soft polyvinyl chloride, fluororesin, or silicone. The distal end of the suction tube 2 is connected to the suction tube connection portion 12 of the graft grasping member 1 and the proximal end thereof is preferably provided with a connector 22 for connection to a suction device (not shown). A material for the connector 22 may be a synthetic resin such as polypropylene, ABS resin, polyvinyl chloride, polyethylene, polyethylene terephthalate, or polycarbonate. A metal bar having pseudo-elasticity may be buried in the wall of the suction tube. In this way, an operation can be performed while handling the suction tube and the tube can be fixed while it is curved so as not to interfere with a surgical operation.

【0020】

The graft grasping member 1 may be provided with the grip 3 on the side wall of the grasping portion to easily handle it. Since the suction tube connection portion 12 may be used as a grip, it cannot be said that the grip 3 is always necessary. However, for example, when it is difficult to insert an operator's hand, the grip is indispensable. The installation position and shape of the grip 3 are not particularly limited but the grip 3 is preferably formed in a tubular shape and connected to the suction tube connection portion 12 provided on the side wall of the grasping portion 11

concentrically to the suction tube 2. The material for the grip 3 may be a metal such as stainless steel or brass. When flexibility is required for the grip 3, the similar synthetic resin to the grasping portion 11 such as polyurethane, polyester, polyethylene, polypropylene, polyamide, fluororesin, or silicone may be used, or a universal joint or flexible hose made of a rigid member such as a metal member may be used. The length of the grip 3 is not particularly limited but is preferably about 100 mm so that it does not interfere with a surgical operation.

【0021】

A description is subsequently given of CABG using the graft grasping device of the present invention with reference to Figs. 6 to 9.

First, the sternum is incised surgically to check the heart, after which a bypass graft (graft 4) is prepared. Thereafter, the anastomosing part of the coronary artery 5 which is seen on the surface of the heart is cut to make a hole 51 as shown in Fig. 7. Next, as shown in Fig. 6, the graft 4 is grasped by a graft grasping device BH and the negative pressure is applied to the lumen 111 of the grasping portion 11 by the suction device (not shown) connected to the suction tube 2. Then, the outer wall of the graft 4 is absorbed by the negative pressure and the anastomosing port 41 is opened. In this state, the graft 4 is sutured with the coronary artery 5 using a suture needle 6 (see Figs. 7 and 8). After the anastomosis,

the slit 112 is opened to pull the graft grasping device BH in a direction indicated by an arrow "a" in order to remove it from the graft 4. CABG is thus completed (see Fig. 9).

【0022】

Incidentally, the anastomosing port 41 shown in Figs. 6 to 9 is formed perpendicular to the axial direction of the graft 4. However, at a clinical site, as shown in Fig. 10, an anastomosing port 81 is formed obliquely with respect to the axial direction of the graft 8 in most cases. In this way, when the anastomosing port 81 is formed like a smooth hood, its opening area becomes large and the amount of the running blood can be increased. However, when the graft 8 having the oblique anastomosing port 81 is grasped by the graft grasping device BH shown in Figs. 1 to 5, the tip 81a of the anastomosing port 81 projects from the porous sheet 22, whereby it may be difficult to keep the anastomosing port 81 open. In this case, as shown in Fig. 11, a graft grasping device BH' having an inclined face 91a formed aslant with respect to the longitudinal direction of a grasping portion 91 is preferably used.

【0023】

When the graft 8 is grasped by using the graft grasping device BH' in such a manner that the anastomosing port 81 and the inclined face 91a become substantially parallel to each other, it can be grasped while the anastomosing port 81 is open as shown in Fig. 12. In Fig. 11, only one end of the grasping portion 91 is formed

obliquely but both ends may be formed obliquely. Note that the graft grasping device BH' having one end formed obliquely and the other end cut at a right angle as shown in Fig. 11 can be used for both a graft having an anastomosing port perpendicular to the axial direction of the graft and a graft having an oblique anastomosing port.

【Brief Description of the Drawings】

【0024】

【Fig. 1】 A front view of an embodiment of the present invention.

【Fig. 2】 A left side view of Fig. 1.

【Fig. 3】 An A-A cross sectional view of Fig. 1.

【Fig. 4】 An enlarged view of a main portion of Fig. 3.

【Fig. 5】 An enlarged B-B cross sectional view of Fig. 2.

【Fig. 6】 A diagram for explaining CABG using a graft grasping device of the present invention.

【Fig. 7】 A diagram for explaining CABG using the graft grasping device of the present invention.

【Fig. 8】 A diagram for explaining CABG using the graft grasping device of the present invention.

【Fig. 9】 A diagram for explaining CABG using the graft grasping device of the present invention.

【Fig. 10】 A diagram showing how to cut a graft obliquely.

【Fig. 11】 A front view of another embodiment of the present invention.

【Fig. 12】 A diagram for explaining a use state of the graft grasping device of the present invention.

【Description of Symbols】

【0025】

1 graft grasping member

11 grasping portion

111 lumen

112 slit

113 communication port

114 recessed portion

115 portion adjacent to distal end and proximal end of grasping portion (margin)

116 portion adjacent to slit (margin)

117 stepped portion (margin)

12 suction tube connection portion

13 porous sheet

131 pore

14 mesh sheet

2 suction tube

21 lumen

22 connector

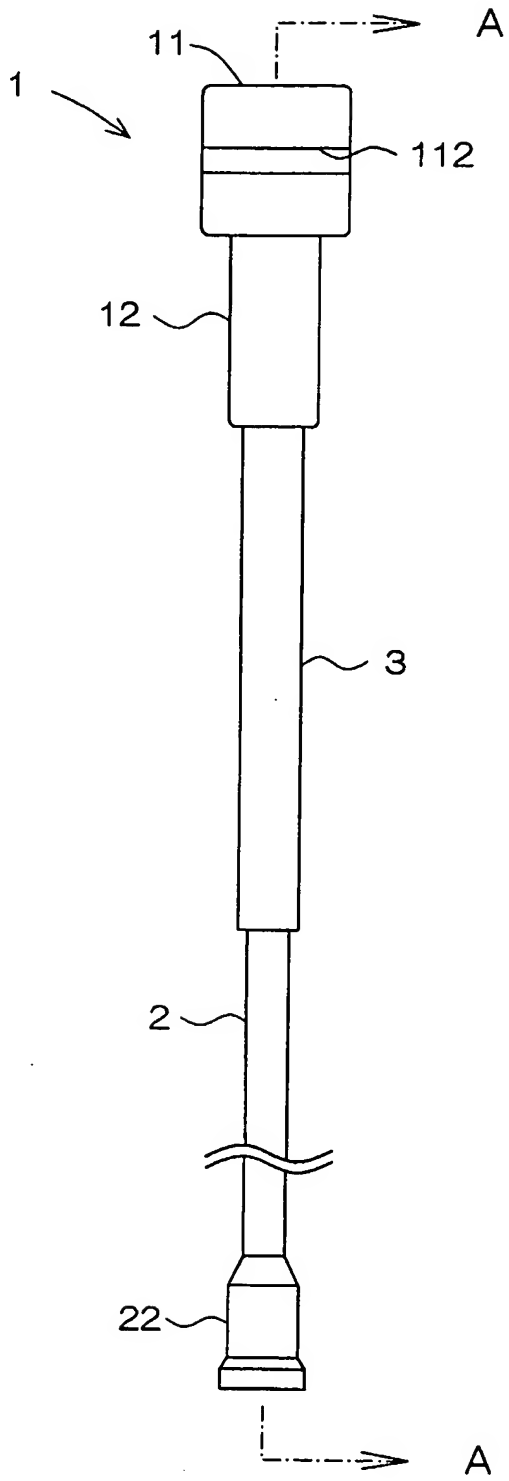
3 grip

4 graft

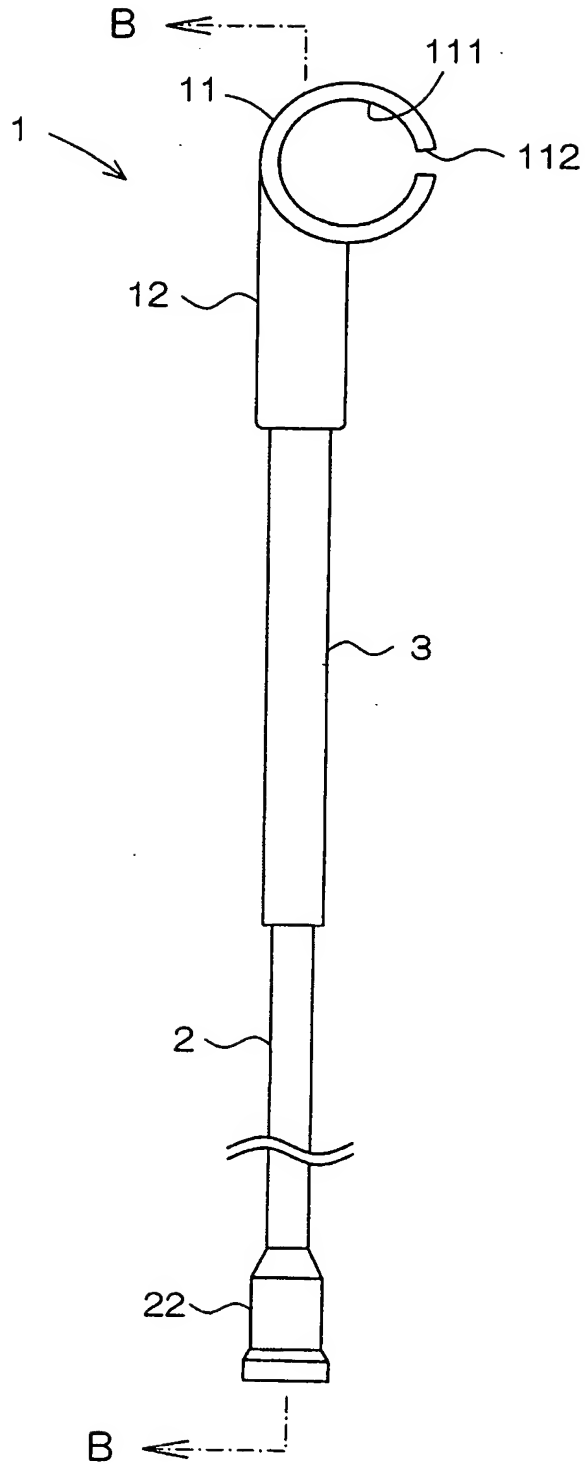
5 coronary artery

51	hole
6	suture needle
7	suture
BH	graft grasping device

【Fig.1】



【Fig.2】



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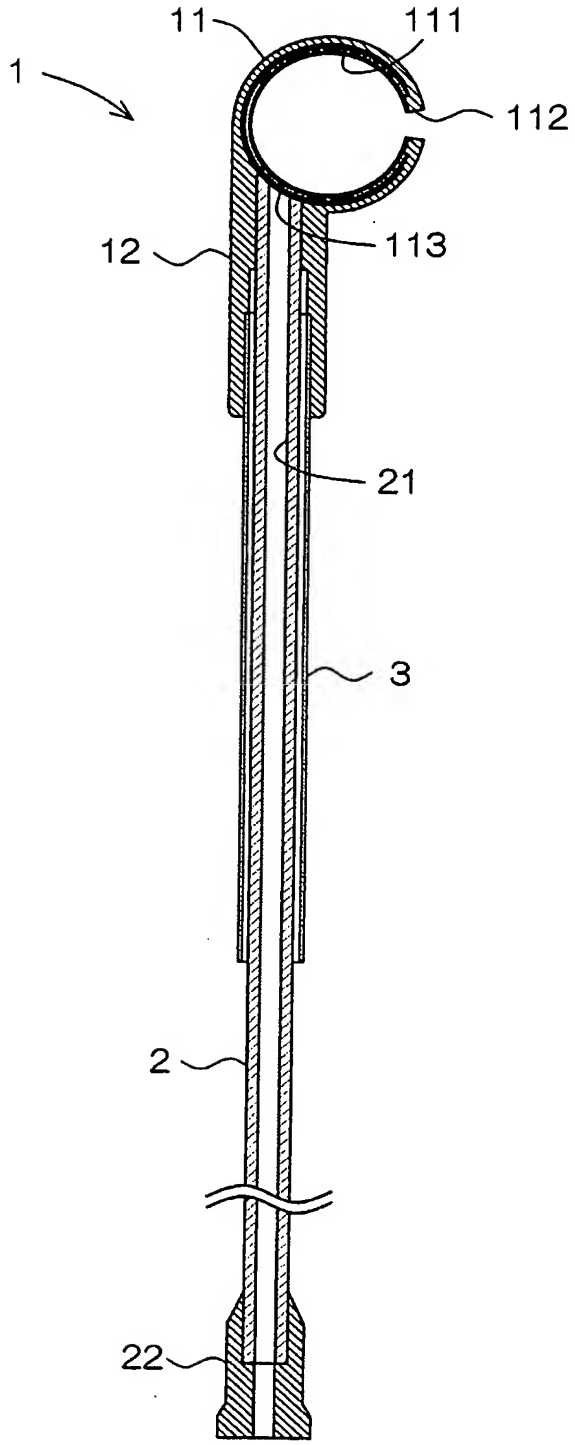
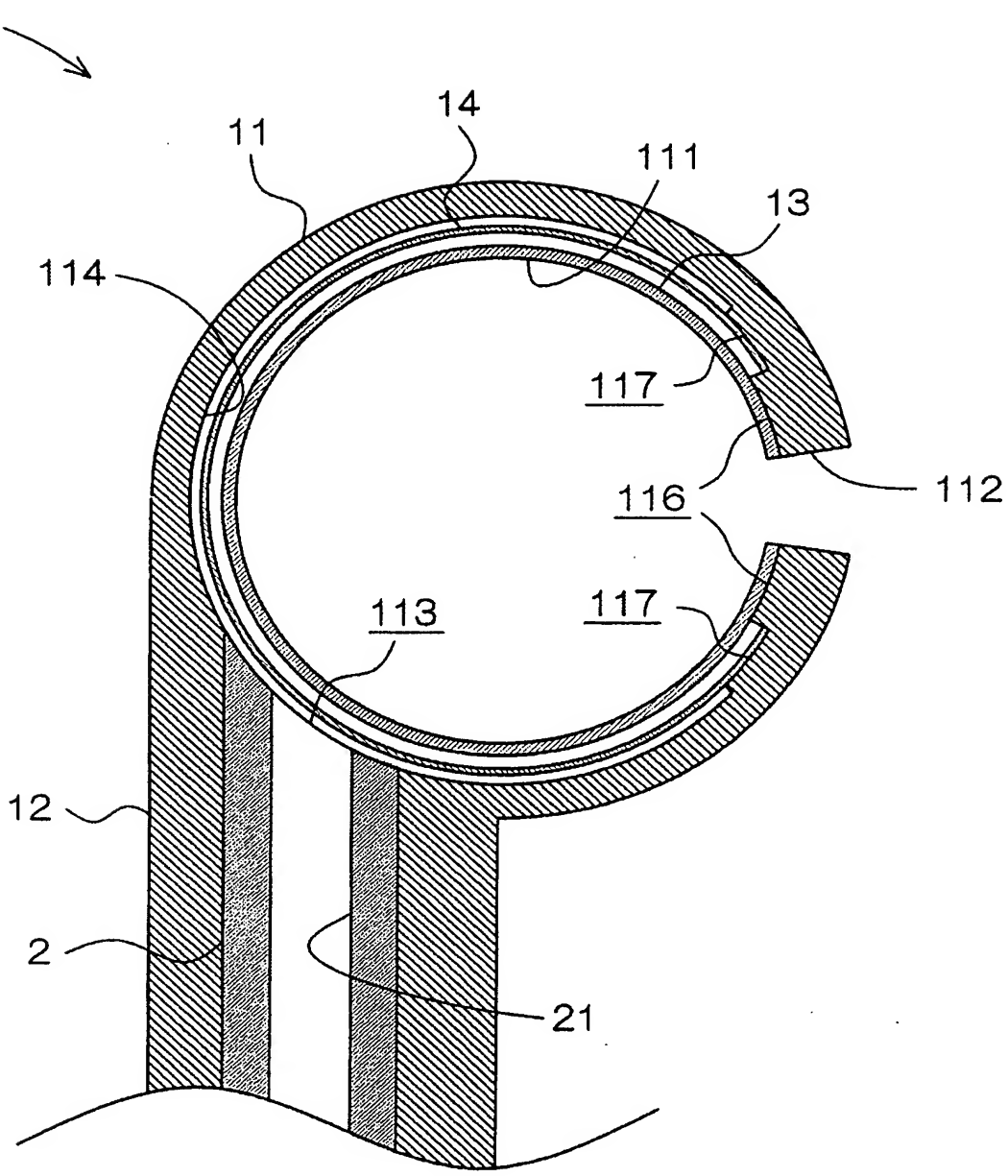
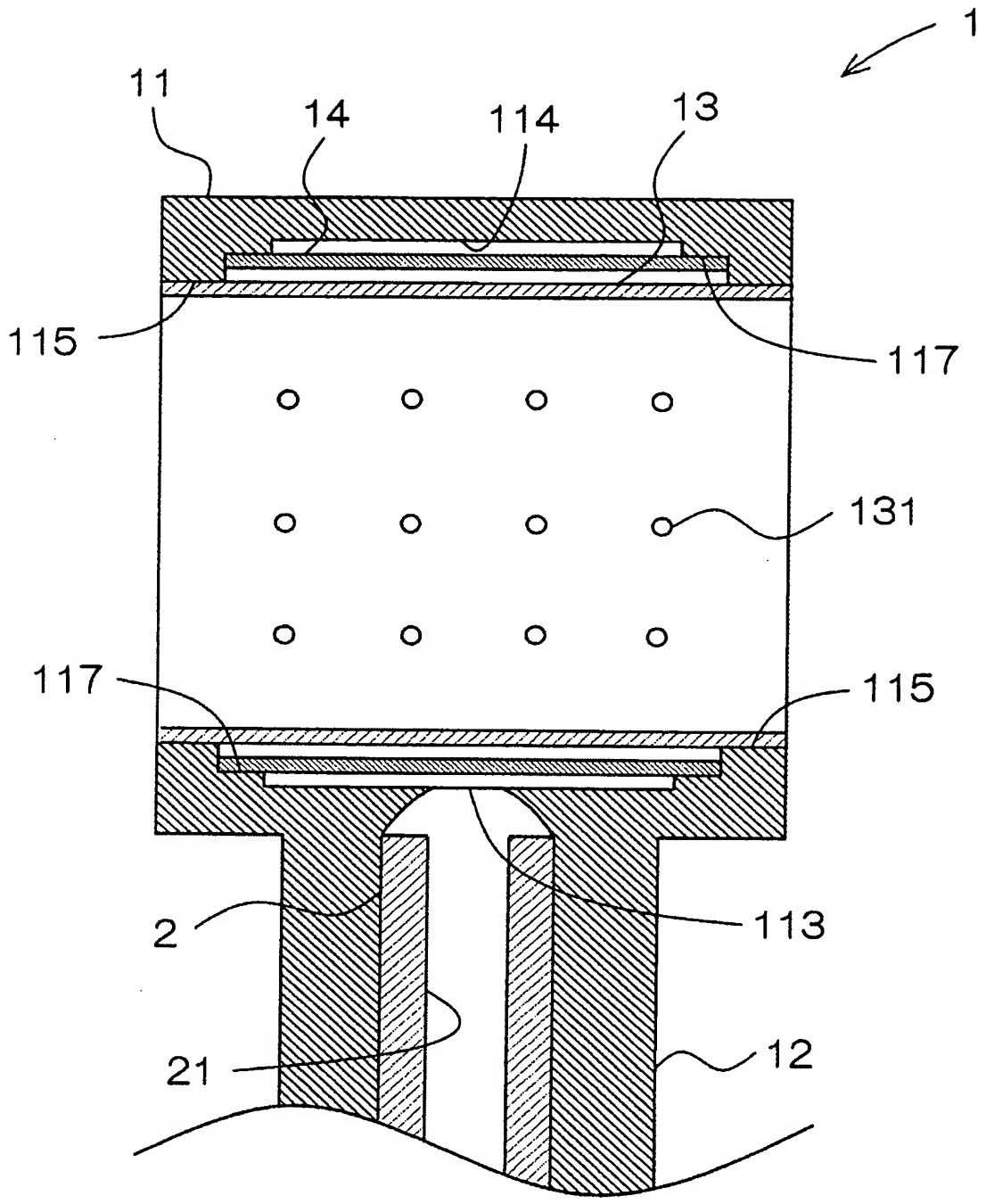


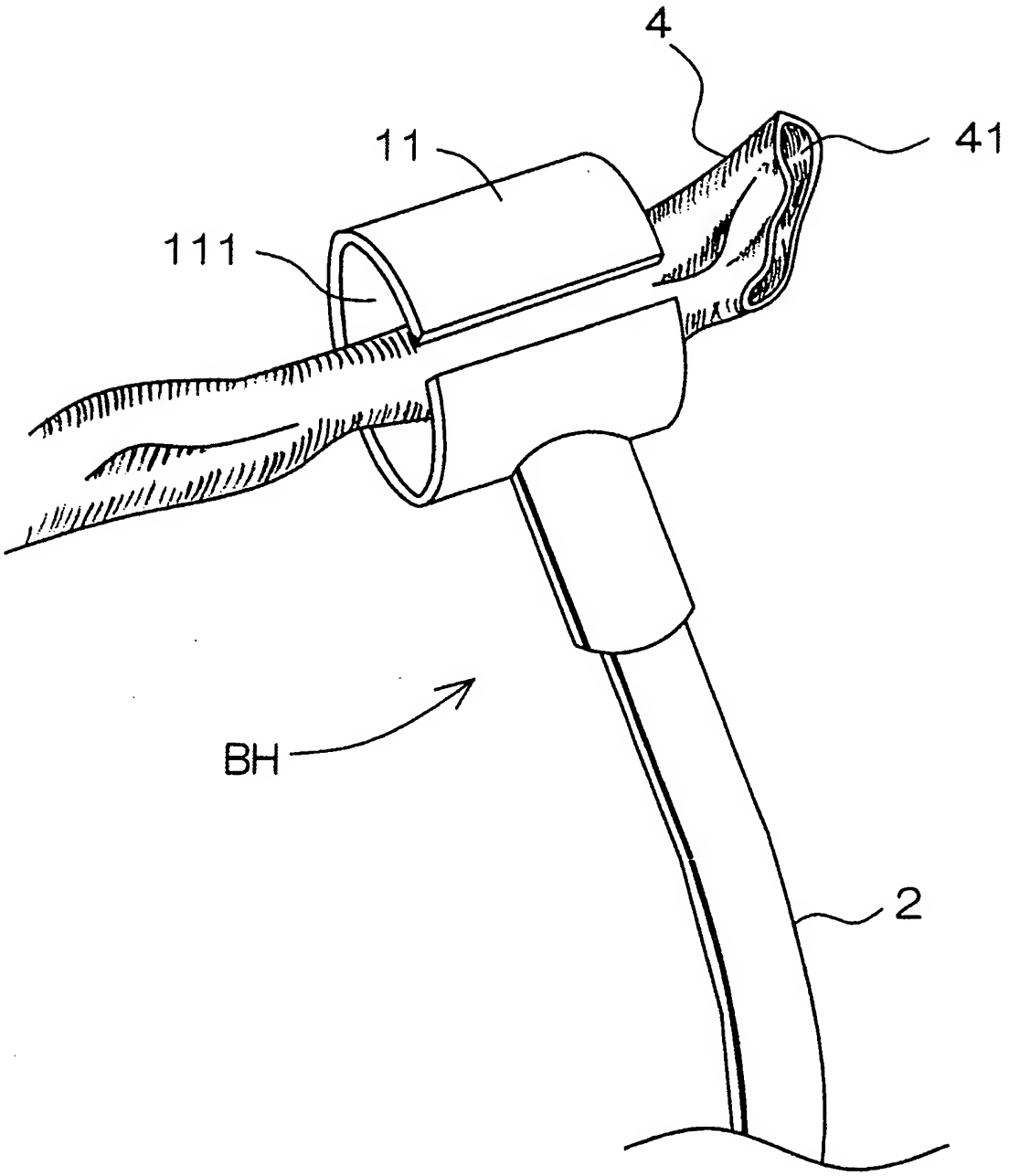
【Fig.4】



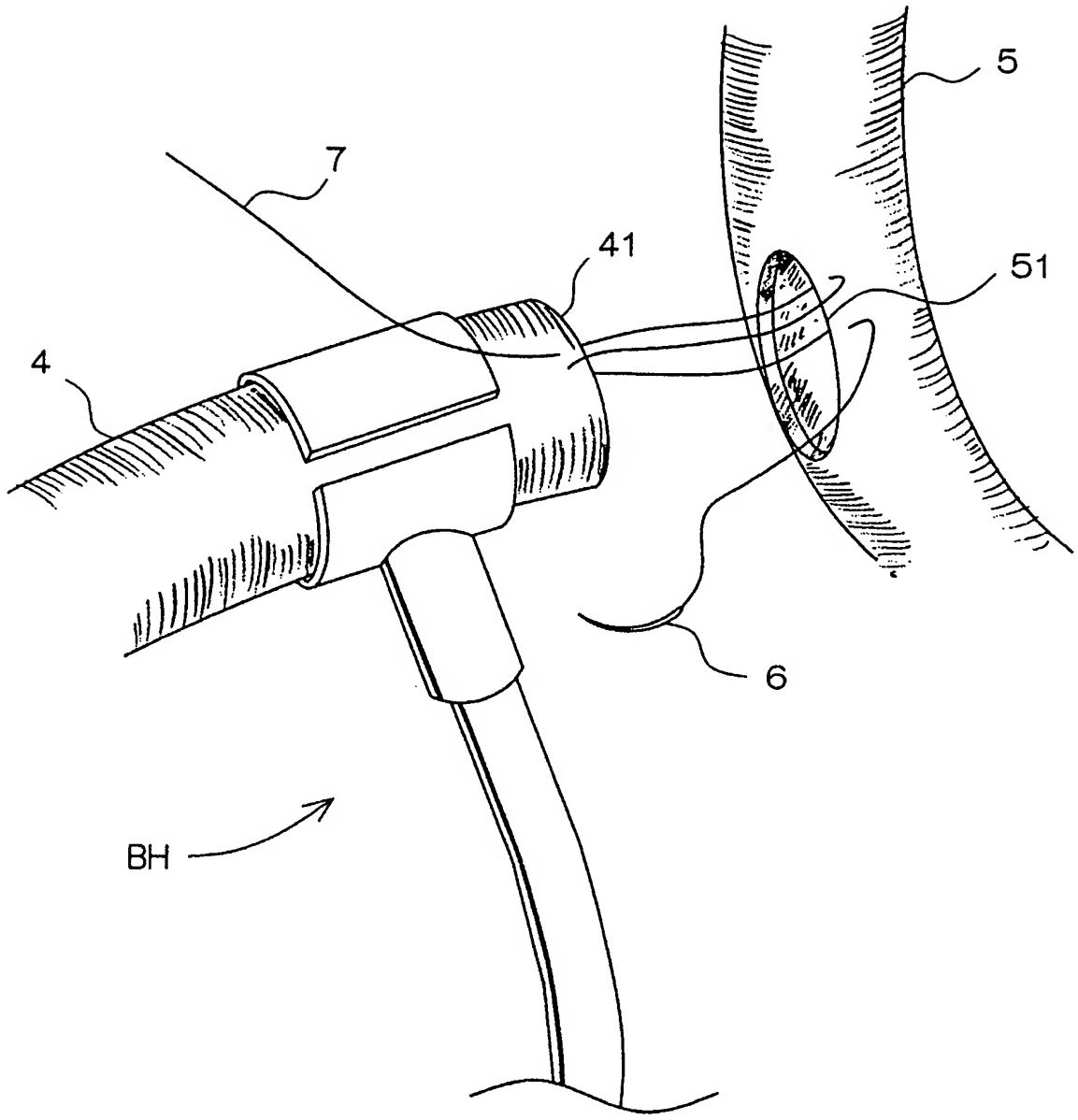
【Fig.5】



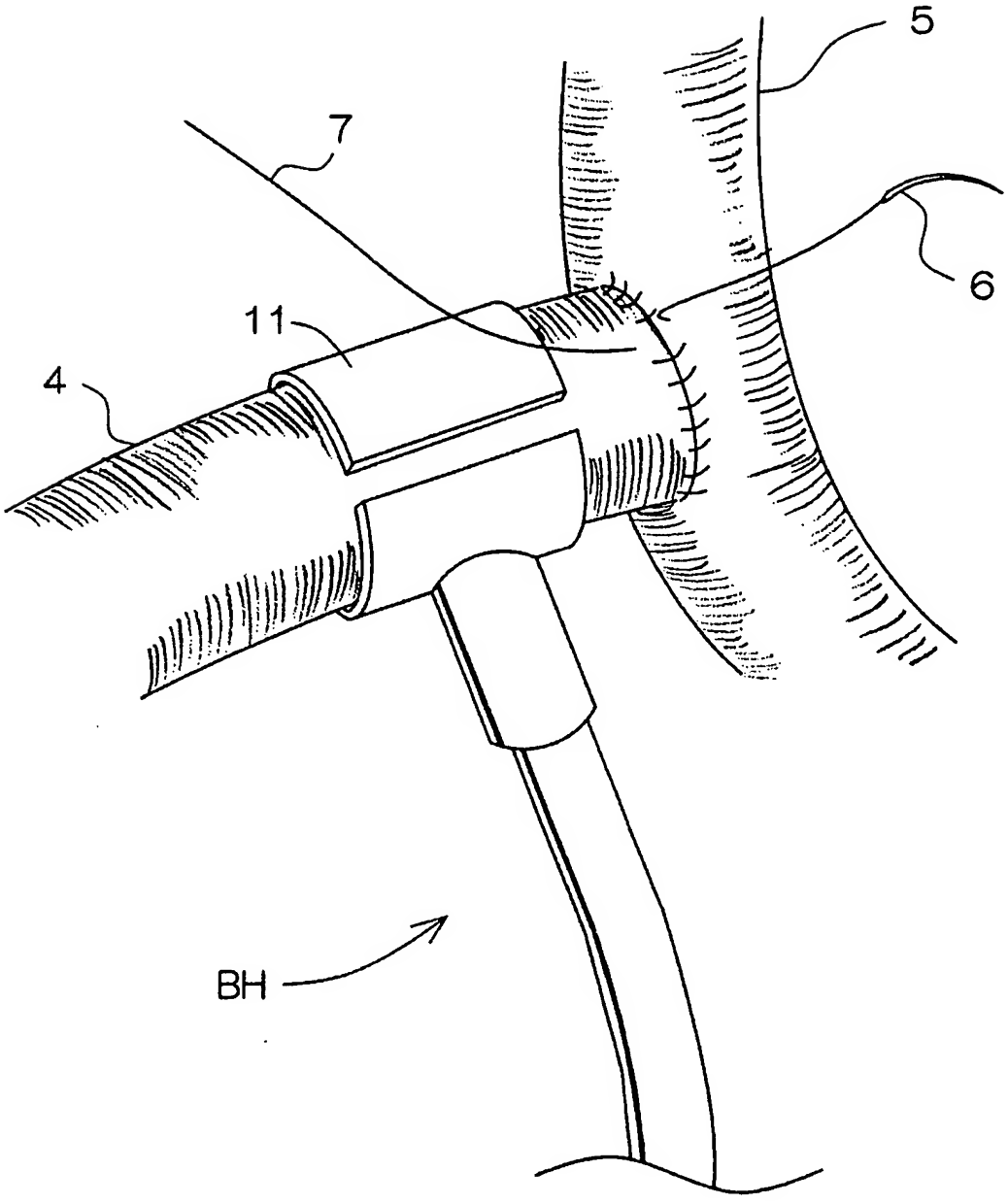
【Fig.6】



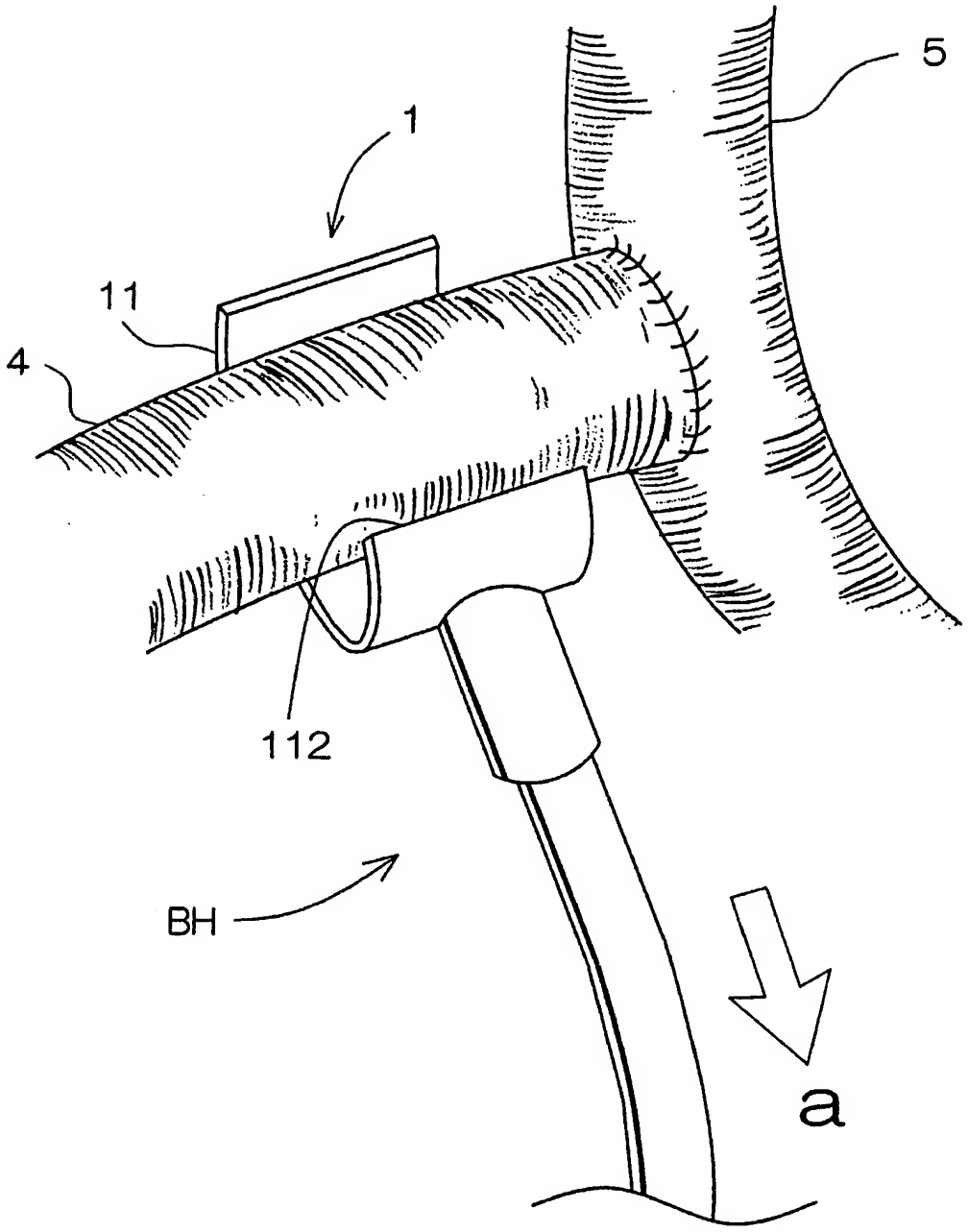
【Fig.7】



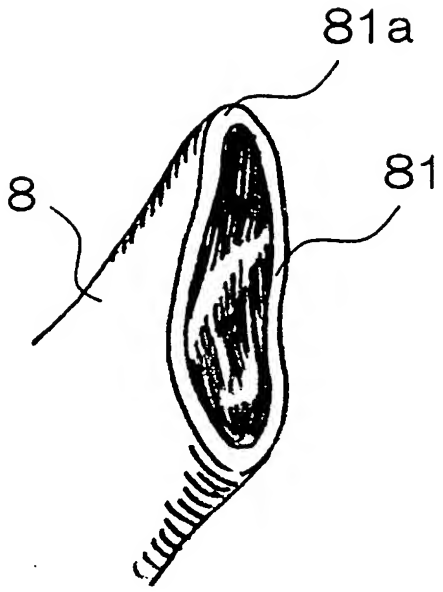
【Fig.8】



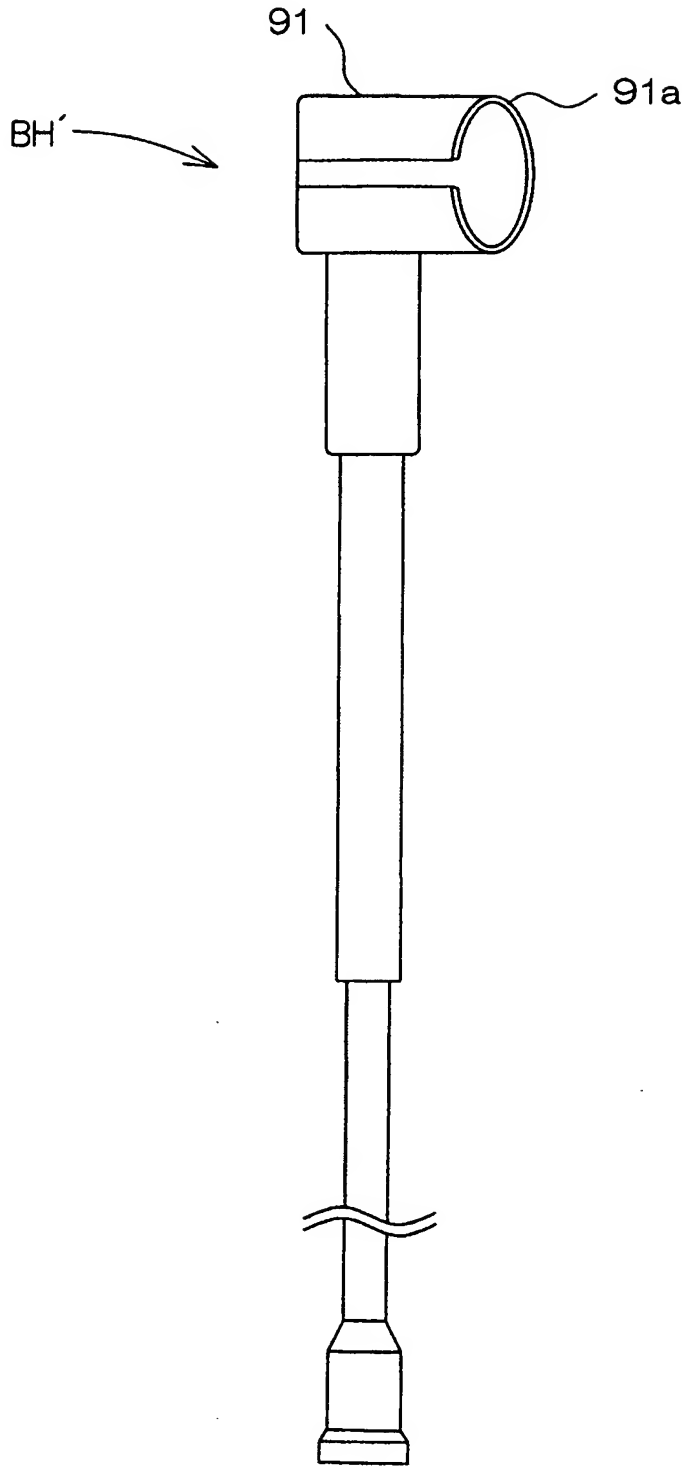
【Fig.9】



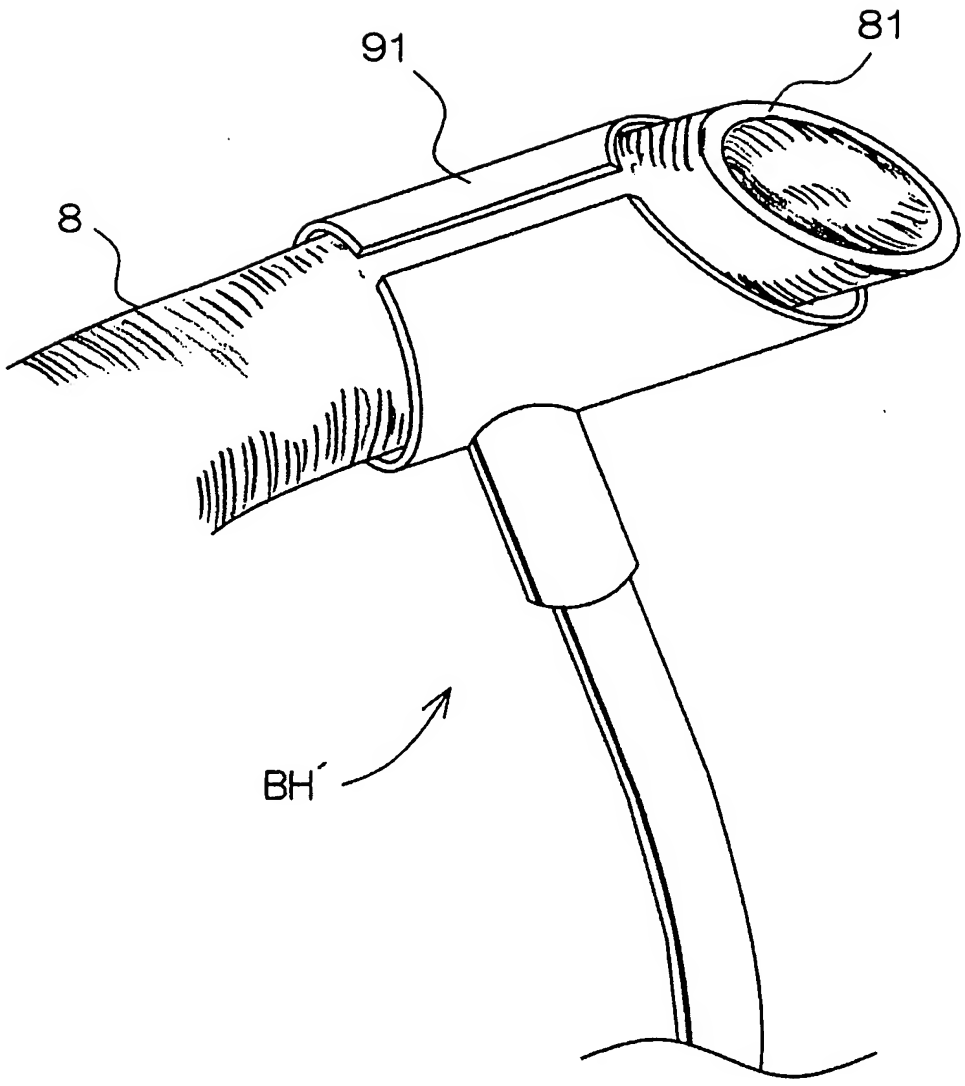
【Fig.10】



【Fig.11】



【Fig.12】



【Name of the Document】 Abstract

【Summary】

【Problem】 To provide a graft grasping device which can open an anatomosing port of a bypass graft to an anatomosing region without causing damage to an intima during a bypassing operation.

【Solving Means】 The graft grasping device includes a graft grasping member 1 including a soft tubular grasping portion 11 having a substantially C-shaped cross section and a suction tube 2 which communicates with a lumen 111 of the grasping portion 11 and is connected to a side wall of the grasping portion 11. A recessed portion 114 including at least a communication port 113 which communicates with a lumen 21 of the suction tube 2 and the lumen 111 of the grasping portion 11 is formed on an inner wall of the grasping portion 11. The recessed portion 114 is covered with a porous sheet 13 and a mesh sheet 14 is interposed between the recessed portion 114 and the porous sheet 13.

【Selected Drawing】 Fig. 4